

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: <i>State of Arizona v. Abbott Labs., Inc., et al.,</i> Subcategory Docket No. 06-CV-11069-PBS	CIVIL ACTION: 01-CV-12257-PBS

**SEPARATE REPLY OF MERCK & CO., INC.
IN SUPPORT OF ITS MOTION TO DISMISS**

Merck’s separate memorandum in support of its motion to dismiss (“Merck Mem.” ECF # 5601) explains how the allegations against Merck in the State of Arizona’s First Amended Complaint (the “Complaint”) differ substantially from those against other defendants. The Complaint premises its AWP fraud claims against Merck entirely on allegations that the published AWP for two self-administered drugs—Zocor® and Vioxx®—do not reflect discounts provided to certain hospitals under “nominal pricing” programs.

Merck’s separate memorandum sets forth the grounds for dismissal of the Complaint as to Merck presented by these unique allegations, in addition to the reasons stated in Defendants’ Joint Memorandum.¹ Arizona failed to respond to Merck’s arguments, other than to assert in a footnote that Merck’s arguments are redundant of those in the joint motion and that Merck improperly raised facts beyond the Amended Complaint. (Pl. Opp. ECF # 5768 at 1, n.1.) Arizona is wrong on both counts.

¹ Merck’s separate memorandum also highlighted that: (1) the Complaint’s allegations as to Merck relate to a time period more than one year before Arizona commenced this action, and would be barred entirely by enforcement of the statute of limitations; and (2) changes to the law relating to nominal pricing render Arizona’s injunctive relief claims moot as to Merck. (Merck Mem. 7-8.) The legal arguments concerning the applicability of the statute of limitations as to Merck are the same as for other defendants. With respect to the second point, Arizona has conceded that its claims apply only to the period prior to the passage of the Medicare Modernization Act of 2003 (Pl. Opp. 3 n.6), which moots the injunctive relief claims as to all defendants.

Merck's motion to dismiss raised no new facts. Rather, it simply pointed out that Arizona's allegations as to Merck, even when taken as true, meet neither the particularity requirements of Rule 9(b), nor the notice pleading requirements of Rule 8. Arizona's specific allegations against Merck are limited to:

- descriptions of two separate "nominal price" programs through which Merck is alleged to have offered discounts for Vioxx® and Zocor® to hospitals (Compl. ¶¶ 400-411);
- an assertion that Merck's sales of those drugs at nominal prices to these hospitals were not reflected in published AWP's (*id.* ¶ 411); and
- a list, in Appendix C to the Complaint, of published AWP's for these two Merck drugs (*id.* ¶ 400 & App. C).

Notwithstanding this Court's clear articulations of the requirements for pleading AWP fraud, *see, e.g., City of New York v. Abbott Labs, Inc.*, MDL No. 1456, 2007 WL 1051642, at *14 (D. Mass. Apr. 2, 2007), the Complaint contains no allegations of spreads for Merck drugs, much less any "good faith estimate of an 'actual' market price from which the spread may be calculated." *Id.*

Arizona argues that the Court's pleading standard should yield to a more general Rule 9(b) standard requiring only that "a plaintiff must set forth more than neutral facts necessary to identify the transaction. The plaintiff must set forth what is false or misleading about a statement, and why it is false." (Opp. at 28 (quoting *Williamson v. Allstate Ins. Co.*, 204 F.R.D. 641, 644 (D. Ariz. 2001)).)² Even if that were the applicable standard, Arizona's allegations against Merck would still be deficient. The only allegation in the Complaint about

² Notwithstanding this Court's own specific rulings in cases virtually identical to this one, Arizona proposes a standard from the pre-*Twombly* decision of a District Court in another Circuit. As this Court has recognized, it is "bound by First Circuit precedent in adjudicating transferred multi-district cases." *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 431 F. Supp. 2d 109, 116 (D. Mass. 2006). The transferor court's constructions of the Federal Rules are no more relevant than would be the decisions of any other District Court outside of the First Circuit. In any event, Arizona's allegations fail under the District of Arizona's articulation of the Rule 9(b) requirements for pleading a claim under the Arizona Consumer Fraud Act, just as the plaintiff in the case cited by Arizona failed under that standard. *Williamson*, 204 F.R.D. at 645.

the AWP for Vioxx® and Zocor®—other than their existence—is that they did not reflect nominal price discounts to hospitals. The Complaint offers no specific allegation as to *why* the AWP for Merck drugs should have reflected sales to hospitals at nominal prices. Indeed, Arizona does not allege that hospitals participating in the nominal pricing program purchased the Merck drugs from *wholesalers* (as opposed to directly) or that any “Patient” within the meaning of the Complaint (*see* Compl. ¶ 1 n.1) made a payment, co-payment, or reimbursement based on AWP to such hospitals for these two drugs.

The closest Arizona comes to articulating why it believes AWP for these drugs should have reflected nominal price discounts to hospitals is the allegation that “various statutes,” including the “Medicaid Rebate Act,” require Merck to “report” (to whom or in what way is not clear) nominal prices. (Compl. ¶ 411.) But, prior to January 1, 2004, the only operative reference to nominal prices in the Medicaid Rebate Act expressly required that manufacturers *not* report nominal prices. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III) (2006); (*see* Merck Mem. 5 & n.3).³ Between January 1, 2004 and January 1, 2007, the Medicaid Rebate Act required that manufacturers report to the Secretary of HHS a list of sales at nominal prices, but, once again, required that manufacturers *not* include such sales in the calculation of reported prices. (*See* Merck Mem. 5 & n.3.)

Accepting as true (for purposes of this motion) Arizona’s allegations that Merck sold two drugs to certain hospitals at nominal prices (Compl. ¶¶ 402, 408, 410, 411), the law does

³ Arizona’s unexplained assertion that Merck “improperly raises facts beyond the Amended Complaint to support dismissal” may have been intended to refer to Merck’s citations to the Medicaid Rebate Agreement and CMS guidance relating to the treatment of nominal price. This Court has, however, properly considered both the Medicaid Rebate Agreement and CMS program releases in deciding motions to dismiss. *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, 339 F. Supp. 2d 165, 178 (D. Mass 2004) (Rebate Agreement); *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 200 (D. Mass 2004) (CMS program releases).

not support Arizona's claim that those transactions should have been reflected in any price reported under the Medicaid Rebate Act, much less in AWP.

CONCLUSION

For the foregoing reasons, as well as those in Defendants' Joint Memoranda, the First Amended Complaint should be dismissed as to Merck.

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the Separate Reply Of Merck & Co., Inc. In Support Of Its Motion To Dismiss was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on January 15, 2009, for posting and notification to all parties.

January 15, 2009

/s/ Robert B. Funkhouser